REMARKS

Claims 70-72, 74-77, 79, 80, 85, 99, 105, 106, 108-111, 113, 114, 119, 133, and 139-148 are pending in the application. Claims 105, 106, 108-111, 113, 114, 119, and 133 have previously been withdrawn. Claims 70-72, 74-77, 79, 80, 85, 99, and 139-148 are currently under examination. No new matter has been added.

Withdrawn Objections And Rejections

Applicants respectfully acknowledge the Examiner's withdrawal of the objection to claims 140-142, as well as the rejections to claims 70-72, 74-77, 79-80, 85, 99, and 139-148 under 35 U.S.C. § 112, second paragraph and under 35 U.S.C. § 103 over Schwarting *et al.* (2001) in view of Pedersen *et al.* (U.S. Pat. No. 6,531,122) and Chang *et al.* (U.S. Pat. No. 5,908,626).

Rejection of Claims 70-72, 74-77, 79, 80, 85, 99, and 139-148 under 35 U.S.C. § 103

Claims 70-72, 74-77, 79, 80, 85, 99, and 139-148 are rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Cruz *et al.* (WO02/100428) in view of Pedersen *et al.* (U.S. Pat. No. 6,531,122) and Chang *et al.* (U.S. Pat. No. 5,908,626). Specifically, the Examiner states:

> [T]here is reasonable expectation of success in treating glomerulonephritis because Cruz et al. discloses that interferon-ß has anti-inflammatory properties and glomerulonephritis is an inflammatory disease. The rationale for using modified interferon-ß of Pedersen et al. and Change et al. is to reduce the allergenicity (column 2, Pedesen) and increase the circulating half life of the protein (Chang et al., column 2) (see the pending *Office Action*, at p. 5).

Applicant respectfully traverses this rejection. In order to establish a *prima facie* case of obviousness, "a reasonable expectation of success is required" (MPEP §2143.02). The Supreme Court in *KSR* stressed that "obviousness cannot be sustained by mere conclusory statements; instead there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *KSR* 127 S.Ct. 1727, 1740 (2007); see also Fed. Reg. Vol. 72, No. 195, p. 57529.

Applicant respectfully submits that at the time of filing there existed no reasonable expectation of success that a method for treating glomerulonephritis in a mammal who is

otherwise free of indications for treatment with IFN-ß, comprising identifying a mammal having glomerulonephritis and administering to the mammal a therapeutically effective amount of an IFN-ß therapeutic, as recited in claim 70 and dependent claims thereof, would be effective, absent the teachings of the present specification.

Similarly, Applicant respectfully submits that at the time of filing there existed no reasonable expectation of success that a method consisting essentially of identifying a mammal having glomerulonephritis and administering to the mammal a therapeutically effective amount of an IFN-ß therapeutic, as recited in claim 143 and dependent claims thereof, would be effective, absent the teachings of the present specification.

In particular, the Examiner cites Cruz *et al.* at page 10, line 5 and page 8, lines 15-20 as allegedly disclosing glomerulonephritis and interferon ß according to the instantly claimed methods. However, the Cruz *et al.* disclosure is drawn to a practically unlimited list of undefined "inflammatory diseases" wherein such conditions comprise a class of *diverse* diseases and need only satisfy any one of 1. triggering an inflammatory response, 2. upregulating any member of an inflammatory cascade, or 3. downregulating any member of an inflammatory cascade (see Cruz *et al.* at page 10, lines 1-3). For example, Cruz *et al.* discloses glomerulonephritis only as part of an extensive list of possible "inflammatory diseases" encompassing widely differing etiologies and disease mechanisms, including "diabetes, artheriosclerosis, inflammatory aortic aneurysm, restenosis, ischemia/reperfusion injury, glomerulonephritis, sacoidosis cancer, restenosis, reperfusion injury, rheumatic fever, systemic lupus erythematosus, rheumatoid arthritis, Reiter's syndrome, psoriatic arthritis, ankylosing spondylitis, coxarthritis, inflammatory bowel disease, ulcerative colitis, Crohn's disease, pelvic inflammatory disease, multiple sclerosis, diabetes, osteomyelitis, adhesive capsulitis, oligoarthritis, osteoarthritis, periarthritis, polyarthritis, psoriasis, Still's disease, synovitis, Alzheimer's disease, Parkinson's disease, amyotrophic lateral sclerosis, osteoporosis, inflammatory dermatosis and wound healing." (see Cruz *et al.* at page 10, lines 4-12). Moreover, Cruz *et al.* discloses application of certain anti-inflammatory agents to an ND4 mouse model, an EAE mouse model, mouse cancer cells, and hepatitis B virus-, herpes simplex virus type 2 virus-, or vesticular stomatitis virus-infected human cells, none of which comprise or represent glomoerulonephritis (see Cruz *et al.* at Examples 1, 2, 5, 8, and 9).

In addition, Cruz *et al.* discloses interferon β only as part of an extensive list of "anti-inflammatory compounds," which include such chemically distinct agents as "aspirin, sodium salicylate, choline salicylate, salicylsalicylic acid, diflunisal, salsalate, indomethacin, sulindac, phenylbutazone, oxyphenbutazone, tolmetin, ibuprofen, feroprofen, flurbiprofen, ketoprofen, mefanamic acid, meclofenamate, piroxicam, naproxen, hydrocortisone, prednisolone, 6-alpha-methylprednisolone, triamcinolone, dexamethasone, betaroethasone, cyclosporine, mycophenolate mofetil, cyclophosphamide, antisense ICAM-1,6-mercaptopurine, tacrolimus, muromonab-CD3, ISAtx247, alefacept, efalizmab, infliximab, azathioprine, methotrexate, sulfasalazine, CT-3™, COX-2 inhibitors, OMS-103HP™, CAB-2™, LDP-01™, IPL550,260™, IPL512,602™, Reliflex™, LFA-1 antagonist, IC74, interferon beta, Avonex™, Betaseron™, Betaferon™ or Rebif™, analogues of Avonex™, Betaseron™, Betaferon™ or Rebif™, interferon compounds, taxanes, Taxol™, microtubule stabilizing agents, analogues of microtubule stabilizing agents, glatiramer acetate, analogues of glatiramer acetate, Novantrone™, Antergren™, Campath™, Adapalene™, nitric oxide synthase inhibitors, anti-TNF or IL-1 compounds and antagonists, antibodies to CD52, retinoic acid antagonists, diacerhein, diacerhein analogues, adhesion peptides, MAF peptides, cytokines, hyaluronic acid (HA) binding peptides, RHAMM peptides, and integrins." (see Cruz *et al.* at page 8, lines 6-23).

Given the lack of a "finite number of identified, predictable potential solutions to the recognized need or problem" (see M.P.E.P. § 2143), Cruz *et al.* does not in any way provide a rational underpinning for selecting interferon β as useful agent for treating glomerulonephritis according to the instantly claimed methods. In other words, Applicant respectfully submits that a skilled artisan reading the Cruz *et al.* disclosure would not have a reasonable expectation of success for choosing glomerulonephritis as a specific "inflammatory disorder," choosing interferon β as a specific "anti-inflammatory compound," and combining the two in order to produce the instantly claimed methods, without impermissible hindsight bias based upon the teachings of Applicant's specification.

Applicant further submits that neither Pedersen *et al.* nor Chang *et al.* cure this deficiency since these documents are limited to disclosing various interferon β preparations.

For at least the reasons set forth above, Applicants respectfully request reconsideration and withdrawal of the rejection.

CONCLUSION

Applicant respectfully submit that the present Response places the claims in condition for allowance. The Examiner may address any questions raised by this submission to the undersigned at (617) 832-1000. If any fees are due, the Commissioner is hereby authorized to credit any overpayment or charge any deficiencies to **Deposit Account No. 06-1448, Reference No. BII-001.01.**

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Respectfully submitted,

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